Council of the European Union

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NOTE

From:	Hungarian delegation
To:	Council
Subject:	Information by the Commission on the Review of the SPC Regulation regarding the introduction of the SPC manufacturing waiver

Hungary requests the addition of an item on "Information by the Commission on the Review of the SPC Regulation regarding the introduction of the SPC manufacturing waiver" under "Any other Business" (item 7. e. of the provisional agenda) at the Competitiveness Council on 29 September 2016.

The Commission in its Communication on *Upgrading the Single Market: more opportunities for people and business* (Single Market Strategy) expressed its intention to strengthen EU-based manufacturing and competitiveness and set as an aim to review the current system of Supplementary Protection Certificates (SPC), especially with a view to introducing and implementing an SPC manufacturing waiver.

These objectives were endorsed by the Council Conclusions on the Single Market Strategy adopted by the Competitiveness Council on 29 February 2016 that stress the importance of an accelerated and intensified approach regarding the adoption and implementation of Union legislation in the Single Market area requiring priority treatment by all three institutions, with a view to achieving ambitious results on the concrete proposals.

Furthermore, the European Parliament resolution of 26 May 2016 on the Single Market Strategy in paragraph 51 urges the Commission not only to introduce but also to implement before 2019 an SPC manufacturing waiver to boost the competitiveness of the European Generics and Biosimilar Industry in a global environment, as well as to maintain and create additional jobs and growth in the EU, without undermining the market exclusivity granted under the SPC regime in protected markets.

We are convinced that in order to save European jobs and to promote growth, we have to avoid the translocation of the manufacturing of pharmaceutical products outside Europe. The present system ensures an up to five and a half-year extension[1] of patent protection to pharmaceutical products patented in the territory of the European Union.

We would welcome a legislative proposal from the Commission to amend the regulation on Supplementary Protection Certificates, allowing for the manufacturing and exportation of pharmaceutical products to third countries within the duration of the patent extension. This amendment could also provide for the so-called stockpiling exception, authorizing generic pharma manufacturers to prepare pharmaceutical products during the SPC term for the purpose of placing them on the market immediately after the expiry of the supplementary protection.

Therefore, an SPC manufacturing waiver could allow the European generic and biosimilar medicines industries to create thousands of high-tech jobs in the EU and many new companies. On the other hand such a waiver would not be detrimental for innovative manufacturers as it concerns exclusively third country markets where no patent protection exists.

[1] Taking into account paediatric SPC extension under Regulation (EC) 1901/2006.

In order to adopt a legislative proposal allowing for an SPC manufacturing waiver and to implement it before 2019, we believe that an accelerated approach is necessary i.e. the proposal should be submitted and negotiated separately from a unitary SPC project.

Taking these objectives into account we request the Commission to inform the Council on the actions it has taken regarding the preparation of a legislative proposal on the introduction of the SPC manufacturing waiver and on the timeline it intends to follow with regard to the launch of the public consultation, the presentation of the impact assessment and the adoption of the proposal.